

Ex 28 - MCKMDL00557196-7249

Plaintiffs' Opposition to Defendants' Motion for Summary Judgment on Proximate Causation Grounds



# State of Prescription Drug Abuse

**Gary Boggs**

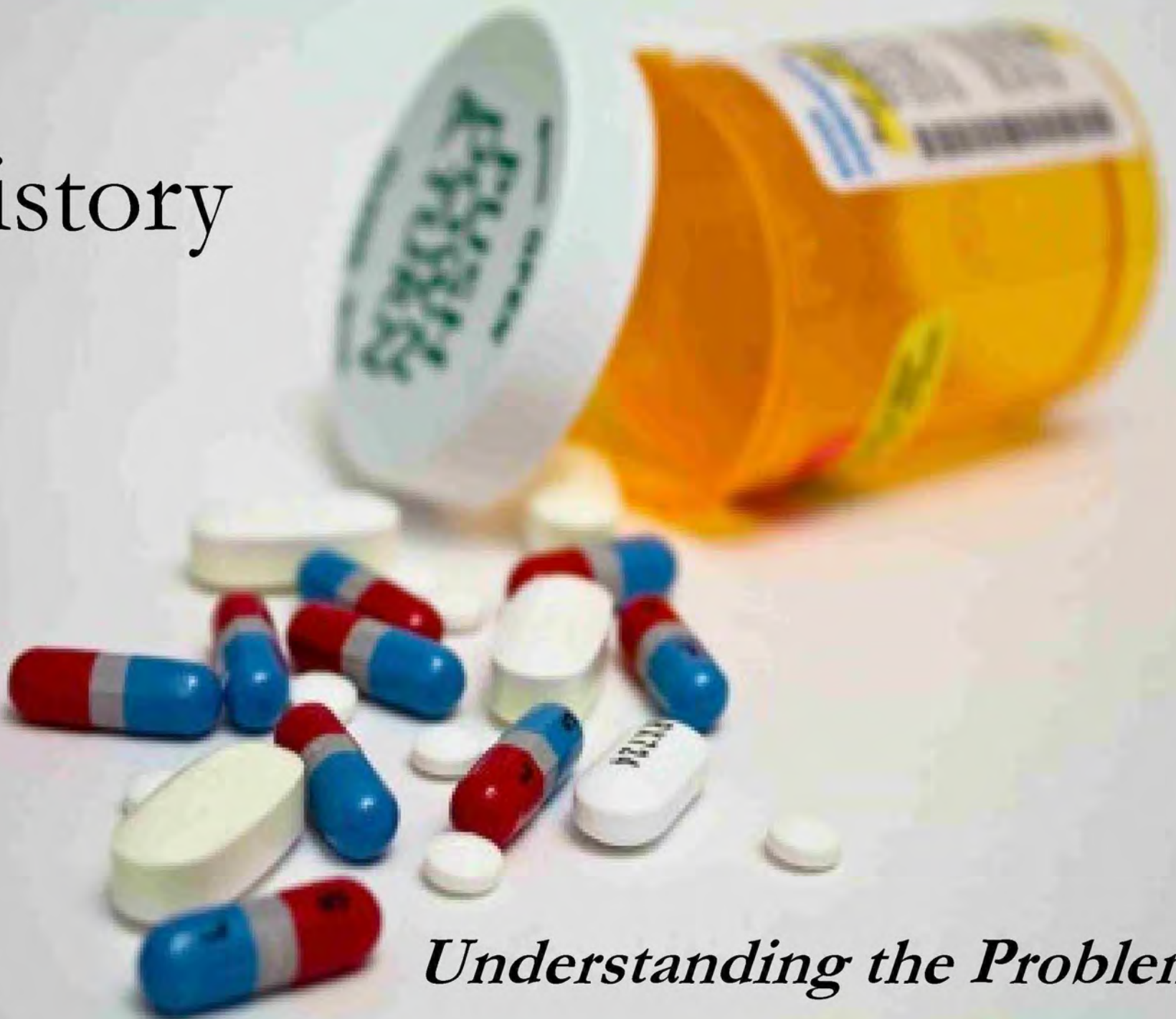
**Olive Branch**

*Protecting America From  
Prescription Drug Diversion*



The Impact of Effective  
Compliance

# History



*Understanding the Problem*



# Collision Course



- OxyContin 1995; Percocet 1999
- Mid 1990's the risk of addiction was significantly underestimated
- Late 1990's doctors began aggressively prescribing pain killers – a radical change in health care behavior
- Manufacturers fueled the use of prescription pain killers





## Purdue Pharma - \$635 Million Fine

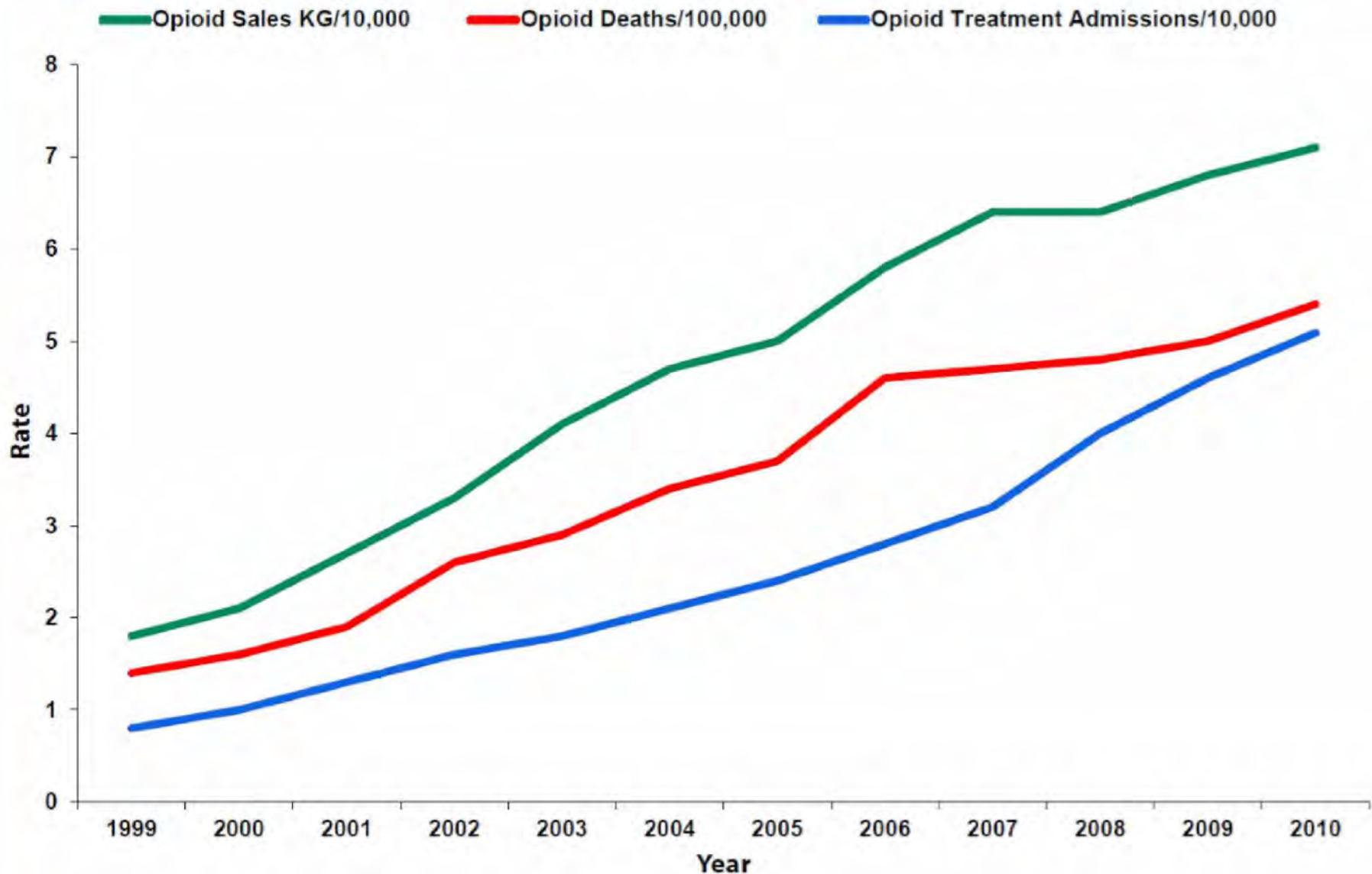
“In 2007, Purdue was accused of fraudulently misleading doctors by claiming, with no proof, that its narcotic painkiller OxyContin was less addictive, less likely to cause withdrawal and less subject to abuse than other pain medications. A court imposed fines and restitution payments totaling \$635 million.” (Journal Sentinel, “Painkiller Boom Fueled by Networking”, February 18, 2012)



# Cephalon - \$425 Million Fine

“In 2008, Cephalon settled an investigation of off-label marketing of three of its drugs, including Actiq, a powerful painkilling product manufactured as a lollipop with the drug fentanyl. The drug was approved for use only by cancer patients who no longer were getting pain relief from morphine-based drugs. But Cephalon allegedly promoted the drug for non-cancer patients with conditions ranging from migraines to injuries. Cephalon agreed to pay a \$425 million penalty.” (Journal Sentinel, “Painkiller Boom Fueled by Networking”, February 18, 2012)

# U.S. Rates of Opioid Overdose Deaths, Sales, and Treatment Admissions, 1999-2010








# The Controlled Substances Act

- Congress carve out for controlled substances
- Establishes a closed system of distribution
- Creates checks and balances between registrants to protect the public health and safety



# Checks and Balances Under the CSA

- Distributors of controlled substances

*“The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances...Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”* (21 CFR §1301.74(b))



# Checks and Balances Under the CSA

## Practitioners

*“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.”*

(21 CFR §1306.04(a))

*United States v Moore*  
423 US 122 (1975)

The image shows two sample prescription forms. The left form is for John Doe, MD, with a DEA# of 000000000 and a LIC. # of ME 0000000. It includes fields for NAME, ADDRESS, AGE, and DATE, and a section for the prescription (R<sub>x</sub>) with handwritten text: "2nd visit 17 Aug", "# 30", "Sig: 1-6-11-11". The right form is also for John Doe, MD, with a DEA# of 000000000 and a LIC. # of ME 0000000. It includes fields for NAME, ADDRESS, AGE, and DATE, and a section for the prescription (R<sub>x</sub>) with handwritten text: "Aug 11 2011", "3/4 cup to".

# Checks and Balances Under the CSA

## Pharmacists – The Last Line of Defense

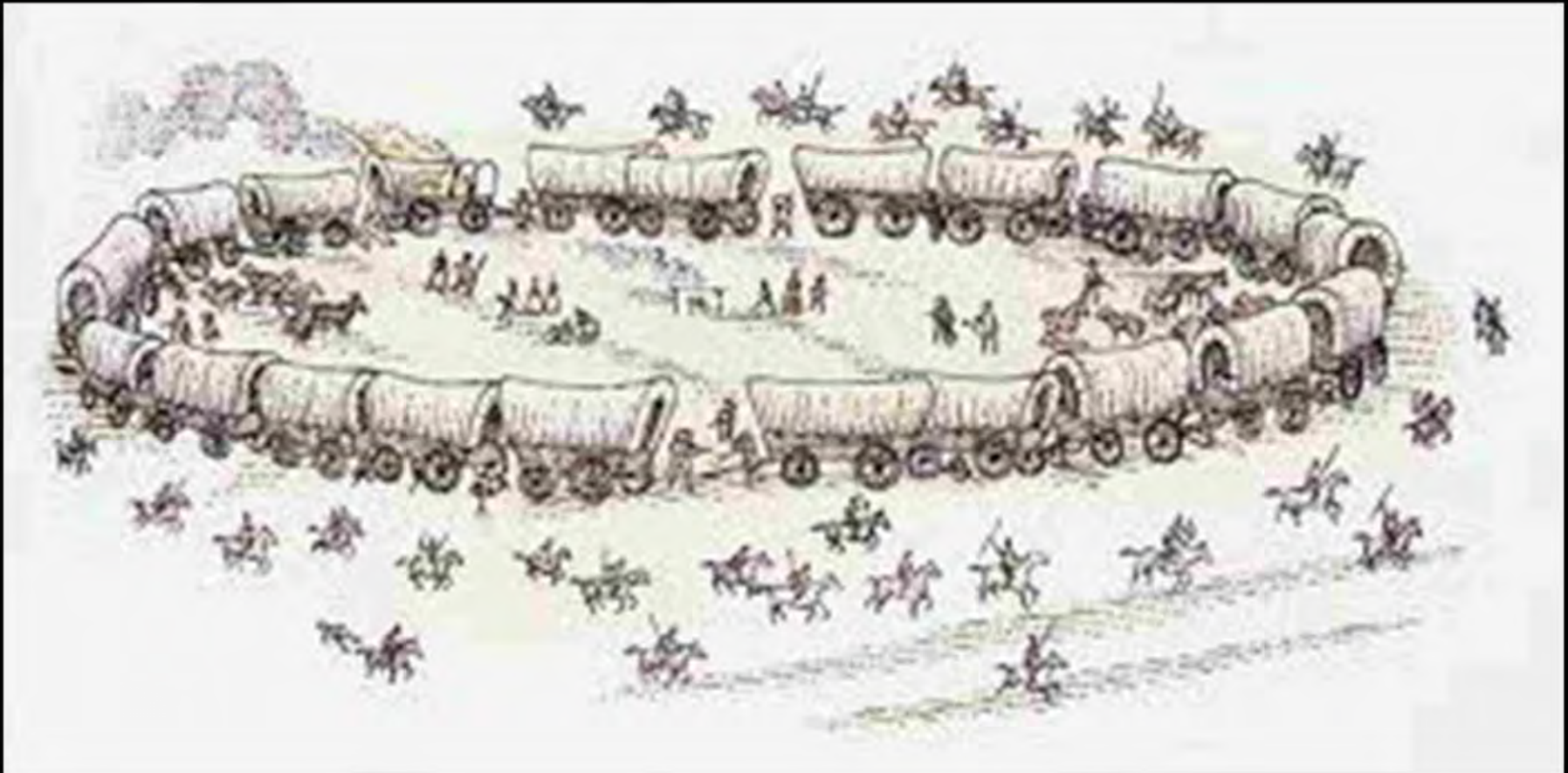
*“The responsibility for the proper prescribing and dispensing of controlled substances is upon the practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.”*

(21 CFR §1306.04(a))



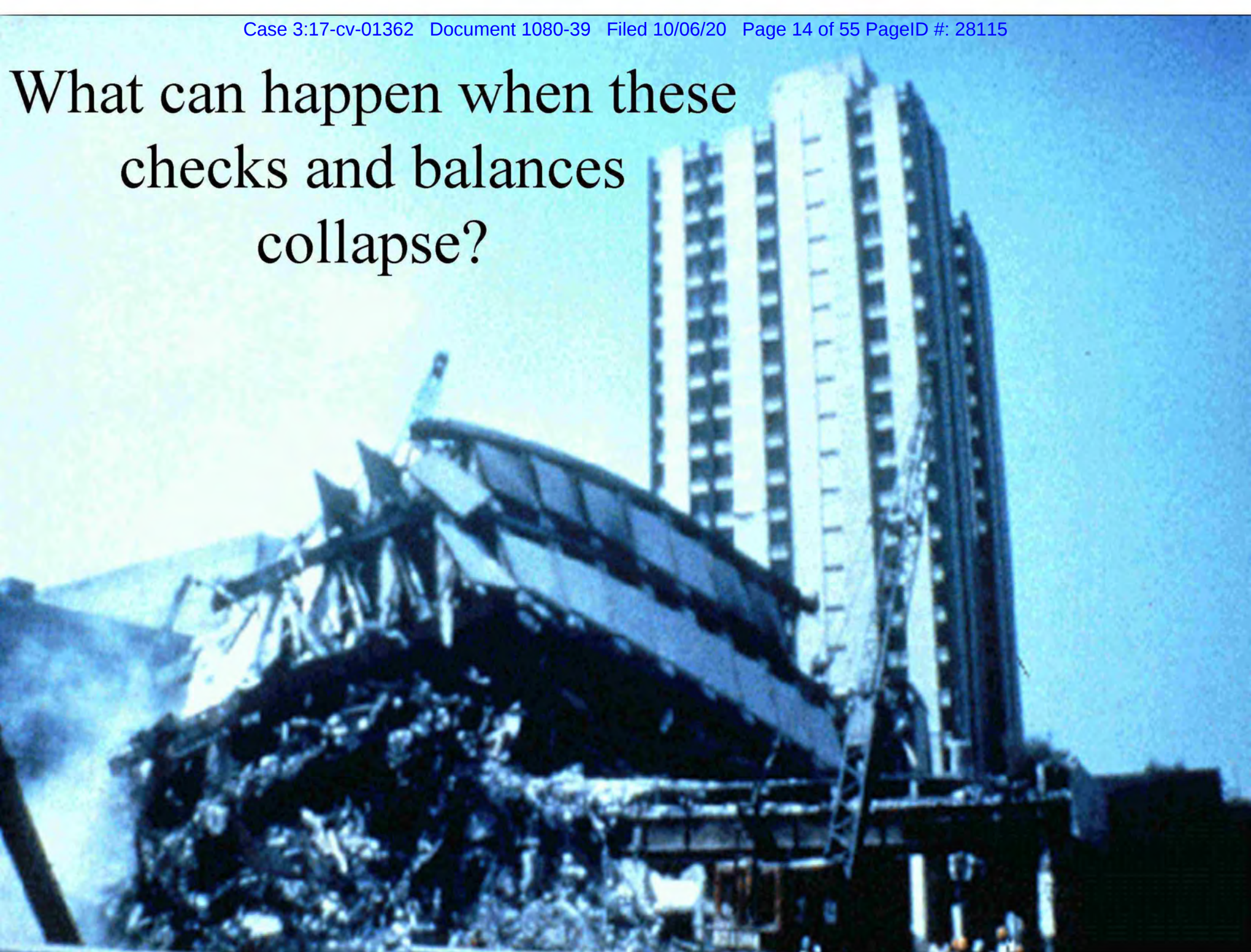


# The Closed System of Distribution





What can happen when these  
checks and balances  
collapse?





# DEA's Perspective





# Purchases of Hydrocodone by Known or Suspected Rogue Internet Pharmacies – 2006

RANK	DEA NUMBER	REGISTRANT NAME	COUNTY	CITY	STATE	ZIP CODE	DOSEAGE UNITS
1	BM9038010	MEDIPHARM-RX, INC	Hillsborough	TAMPA	FLORIDA	33614	15,596,380
2	BA8622284	AVEE PHARMACY INC	Pinellas	CLEARWATER	FLORIDA	33765	9,077,810
3	BA9323089	ACCUMED RX INC	Hillsborough	TAMPA	FLORIDA	33614	8,760,876
4	BN3795892	NEWCARE HOME HEALTH SERVICES	Baltimore City	BALTIMORE	MARYLAND	21213	5,876,300
5	BP8680779	PMSI INC	Hillsborough	TAMPA	FLORIDA	33619	5,718,200
6	BE9086085	ELITE PHARMACY INC	Jefferson	RIVER RIDGE	LOUISIANA	70123	4,892,900
7	BU8619491	UNIVERSAL RX	Hillsborough	TAMPA	FLORIDA	33634	4,733,290
8	BM9085487	MEDCENTER, INC	Polk	LAKELAND	FLORIDA	33813	4,564,480
9	BU6696073	UNITED PRESCRIPTION SERVICES	Hillsborough	TAMPA	FLORIDA	33612	4,220,840
10	BR9174878	RKR HOLDINGS INC DBA MEDICHEM RX	Pinellas	CLEARWATER	FLORIDA	33759	3,819,320
11	BV9062097	VIN-KASH INC			FLORIDA	33610	3,044,160
12	BQ9455420					33809	3,039,490
13	BP9000338					70123	2,750,000
14	BG9541548					34652	2,664,120
15	BN4151279	NATION			FLORIDA	33613	1,902,900
16	BC9458539	CRJ PHARMACY INC		LAKELAND	FLORIDA	33801	1,726,020
17	BA7716802	AKSHAR CHEMISTS DBA THE MEDICINE SHOPPE	Hillsborough	TAMPA	FLORIDA	33612	1,619,765
18	BJ7340906	JEN-MAR PHARMACY SERVICES	Hillsborough	TAMPA	FLORIDA	33604	1,570,350
19	BB8092164	BI-WISE DRUGS INC	Pinellas	TARPON SPRINGS	FLORIDA	34689	1,464,900
20	BW8909814	WOODY PHARMACY WATERSIDE	Lincoln	DENVER	NORTH CAROLINA	28037	1,402,450
21	BB8134570	BENAK INC DBA TAMPA DRUGS	Hillsborough	TAMPA	FLORIDA	33617	1,282,800
22	BM9591745	MEDASSIST RX, LLC	Hillsborough	TAMPA	FLORIDA	33619	1,272,860
23	BY9713276	YPM TOTAL CARE PHARMACY	Polk	LAKELAND	FLORIDA	33813	1,039,400
24	BH9157719	HEALTH E CHOICE, LLC	Pasco	WESLEY CHAPEL	FLORIDA	33543	1,030,050
25	BH3228156	HOME IV CARE OF NC INC DBA WOODY PHARMACY	Iredell	MOORESVILLE	NORTH CAROLINA	28117	902,500
26	BD5896103	DRM ENTERPRISES INC D/B/A MARTIN DRUG	Polk	LAKELAND	FLORIDA	33815	867,800
27	BI7564594	INTRAMED	Broward	HOLLYWOOD	FLORIDA	33021	865,700
28	AB9764095	BOULEVARD PHARMACY	Los Angeles	ENCINO	CALIFORNIA	91436	798,100
29	BA9135395	ARMENIA PHARMACY INC	Hillsborough	TAMPA	FLORIDA	33604	793,350
30	BL8468717	LURD'S INCORPORATION DBA DOCTOR'S CHOICE PHARMACY	Pasco	NEW PORT RICHEY	FLORIDA	34652	583,400
31	BF9172925	FLORENCE PHARMACY NORTH	Ravalli	FLORENCE	MONTANA	59833	362,000
32	BT5771933	TRELLES PHARMACY MANAGEMENT	Hillsborough	TAMPA	FLORIDA	33619	162,000
33	BM9657810	METRAGEN PHARMACEUTICALS INC.	Broward	DEERFIELD BEACH	FLORIDA	33441	112,600
34	BM9038008	MEDIPHARM-RX, INC	Hillsborough	TAMPA	FLORIDA	33614	49,600

98,566,711

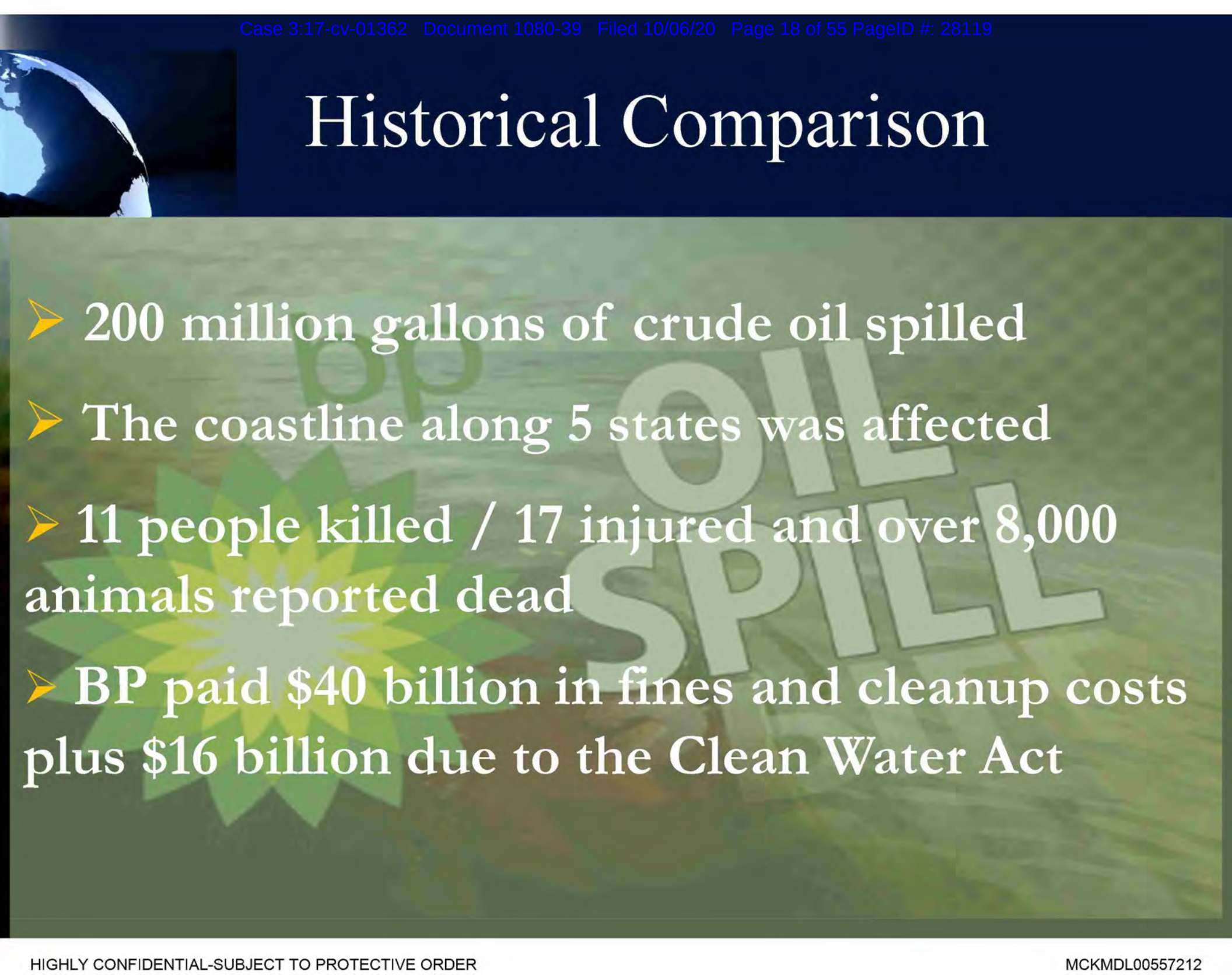


# Explosion of “Pain Clinics” Affecting the Entire East Coast and Midwest





# Historical Comparison

- 
- 200 million gallons of crude oil spilled
  - The coastline along 5 states was affected
  - 11 people killed / 17 injured and over 8,000 animals reported dead
  - BP paid \$40 billion in fines and cleanup costs plus \$16 billion due to the Clean Water Act



# Florida Pill Mills Resulting “Oxy Spill”

2009 and 2010:

- Average purchase of oxycodone products by a pharmacy – 63,294 d.u. per year
- In Florida the top 100 pharmacies each purchased more than 1,226,460 d.u. – per year
- 44% of all oxycodone 30mg products were distributed to Florida in each year







Oxycodone Deaths in Florida Rose from 340 in 2005 to 1,516 in 2010 – a 346% Increase!





UNITED STATES

Drug Enforcement Administration

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## NEW YORK NEWS

September 20, 2013

Contact: Public Information Officer

Number: 212-337-2906

## New York Methodist Hospital Agrees to Implement Compliance Program to Settle Civil Claims under the Controlled Substances Act

*Hospital's residents issued improper prescriptions for Adderall, a highly addictive stimulant*

**SEP 20 (BROOKLYN, N.Y.)** – Loretta E. Lynch, United States Attorney for the Eastern District of New York and Brian R. Crowell, Special Agent in Charge of the U.S. Drug Enforcement Administration, New York Division, announced today the filing and settlement of a civil action by the United States against New York Methodist Hospital ("NY Methodist"). Under a Consent Judgment, NY Methodist has agreed to implement measures designed to prevent the issuance of NY Methodist prescriptions in violation of the Controlled Substances Act and paid a civil penalty in the amount of \$70,000.

In the civil action, the United States alleges that between May 2008 and July 2010, medical residents employed by NY Methodist issued a total of 194 prescriptions for Adderall without a legitimate medical purpose. The medical residents employed by NY Methodist issued the prescriptions on prescription forms bearing the name of NY Methodist. The residents, acting with other individuals, then filled the prescriptions at local pharmacies. The residents themselves consumed some of the Adderall obtained by filling the prescriptions. The remainder of the Adderall was sold, either on Craigslist or in hand to hand transactions. In 2012, in a related criminal prosecution in this district, a former NY Methodist medical resident was convicted for conspiracy to distribute and possess with intent to distribute Adderall.

Adderall is a stimulant that contains amphetamine salts, is classified as a Schedule II controlled

- New York
- 2008-2010
- Hospital
- Medical Residents
- Adderall
- Prescriptions issued without legitimate medical purpose





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## MIAMI NEWS

Septembr 24, 2013

Contact: Public Information Officer

Number: 954-660-4602

**Pasco County Pharmacist Sentenced for Illegally Distributing Pain Medications**

**SEP 24 (TAMPA, Fla.)** – Mark R. Trouville, Special Agent in Charge (SAC), Drug Enforcement Administration (DEA), Miami Field Division, and A. Lee Bentley, III, Acting United States Attorney for the Middle District of Florida, announces that United States District Judge Susan Bucklew today sentenced Edward Benjamin Alister Beckles (59, Pasco County) to four years in federal prison for distributing oxycodone. As part of his sentence, the court also entered a money judgment in the amount of \$175,000 from the criminal proceeds. Beckles was also ordered to serve a two-year term of supervised release. Beckles pleaded guilty on March 26, 2013.

In 2010, according to court documents the DEA and the Pasco County Sheriff's Office (PCSO) began an investigation to identify members of a large oxycodone distribution ring. As a result of the investigation, 33 individuals were arrested and prosecuted.

From August 2009 through January 2012, individuals obtained fraudulent prescriptions for oxycodone and had them filled at Ed's Family Friendly Pharmacy in New Port Richey. Beckles, a licensed pharmacist and owner of the pharmacy, filled the prescriptions knowing they were fraudulent. During the investigation, Beckles provided investigators with a computer printout that showed the pharmacy made in excess of \$130,000 in a 45-day period from the illegal sale of oxycodone. Approximately 210 fraudulent prescriptions, each for 270 pills, were filled in the 45-day period.

- Florida
- 2009-2012
- Pharmacy
- Pharmacist/owner
- Oxycodone
- Filling prescriptions known to be fraudulent
- 56,700 pills diverted in just a 45-day period





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## PHILADELPHIA NEWS

September 24, 2013

Contact: Public Information Officer

215-800-7761

**Doctor Sentenced for Running Pill Mill and Contributing to a Death**

**SEPT 24 (PHILADELPHIA)** – Dr. Norman Werther, 73, of Ft. Washington, PA, was sentenced today to 25 years in prison for distribution of a controlled substance resulting in death and more than 300 counts stemming from his pill mill operation. A federal jury convicted Werther on June 11, 2013 of 184 counts of illegally distributing oxycodone, 116 counts of money laundering, six counts of conspiracy to distribute controlled substances, and one count of maintaining drug-involved premises.

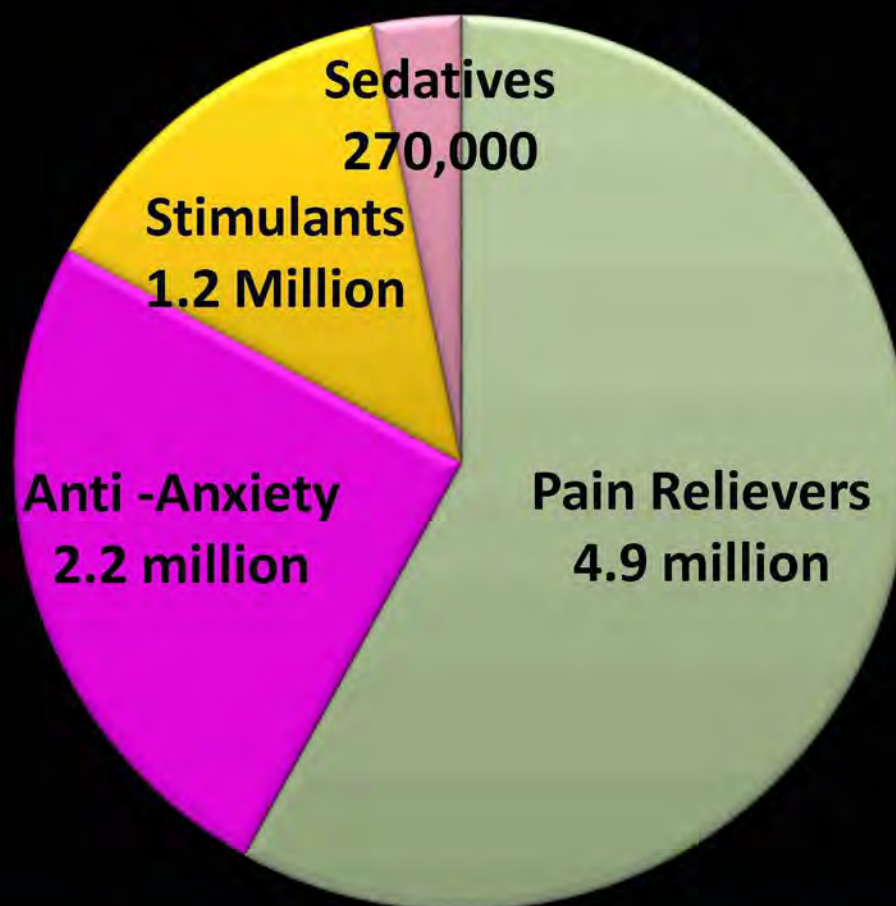
Werther was part of a multi-million dollar drug conspiracy involving illegal prescriptions, phony patients, and multiple drug trafficking organizations. At the time, Werther was a Montgomery County physician, running a physical therapy and rehabilitation practice in Willow Grove. He conspired with six separate groups of drug dealers. Werther was involved in the drug conspiracy between February 2009 and August 2011. The operation resulted in the illegal distribution of more than 700,000 pills containing oxycodone. At least one of the drug trafficking organizations working with Werther trafficked pills valued at more than \$5 million that Werther illegally prescribed.

"Instead of using his medical license to help people, Dr. Werther chose to generate tremendous profits by putting hundreds of thousands of pills on the street illegally," said First Assistant US Attorney Louis Lappen. "In one case, as the jury found, Dr. Werther's criminal enterprise and blatant disregard for the safety of the community caused the death of a patient whom Dr. Werther knew had a history of drug addiction. The court's sentence today will send a message to a growing community of pharmaceutical drug pushers that the justice

- Pennsylvania
- 2009-2011
- Practitioner
- Oxycodone
- Writing illegal prescriptions for pseudo-patients.
- More than 700,000 pills diverted.

# Prescription Drug Abuse – 2012

## 6.8 Million Americans



■ Pain Relievers ■ Anti-Anxiety ■ Stimulants ■ Sedatives

Source: 2012 NSDUH





# A National Epidemic

- More than 45 people die per day from prescription opioids
  - From 4,030 in 1999 to 16,651 in 2010
  - 1 in 20 people in the U.S. reported using prescription painkillers non-medically in the past year
  - 6,700 new initiates per day in 2012
- Economic impact to America >\$57 billion dollars per year



# Are We Contributing to the Problem?

- A distributor ships:
  - Only the specific drug of choice,
  - In an exorbitant amount,
  - In the primary strength,
  - To the known epicenter of diversion,
  - To a customer they had never dealt with in the past – AND – then doing it repeatedly





# Effective Compliance?

- A distributor ships multiple orders:
  - In the primary strength,
  - To the known epicenter of diversion,
  - To a customer suspected of being involved in diversion, and
  - Charging the customer more than normal for the drug of choice in an attempt to discourage the customer from ordering from them.



# Recurring Comments

- Won't talk to us
- Won't tell us what we need to do
- Won't tell us what to look for
- Won't tell us who the suspicious registrants are
- Won't approve our SOM system
- Won't share ARCOS data with us
- The customer's registration was still valid...so
- Why couldn't we have been warned first
- We're too busy to look at everything
- If we don't sell it our competitors will





# Communication / Advance Warnings

- Distributor Initiative
- Reminder letters sent to industry
- Host industry conferences
- Speak at various conferences
- Meetings with HDMA and industry reps
- Educate downstream registrants to do their part
- Congressional testimony



# ARCOS data

- Importance of knowing your own data
- Early warning sign for an emerging trend?





# Sharing Suspicious Registrant Info

- May involve ongoing criminal investigation
- Info may be protected under Grand Jury rules
- Requirement to identify and report suspicious orders does not always involve diversion
  - In many instances the registrant knew or should have known what was happening by way of their own data
- Previous litigation for doing so



# Approving SOM Systems

- One-size-fits-all doesn't work
- Allowing for differences in business models
- Allowing for innovation and flexibility
- Prevent a false sense of security
- Doing so might create complacency
- Responsibility of each registrant





# What is the Agency Looking to Accomplish?



# Protect the Public Health and Safety – Stop the Hemorrhaging

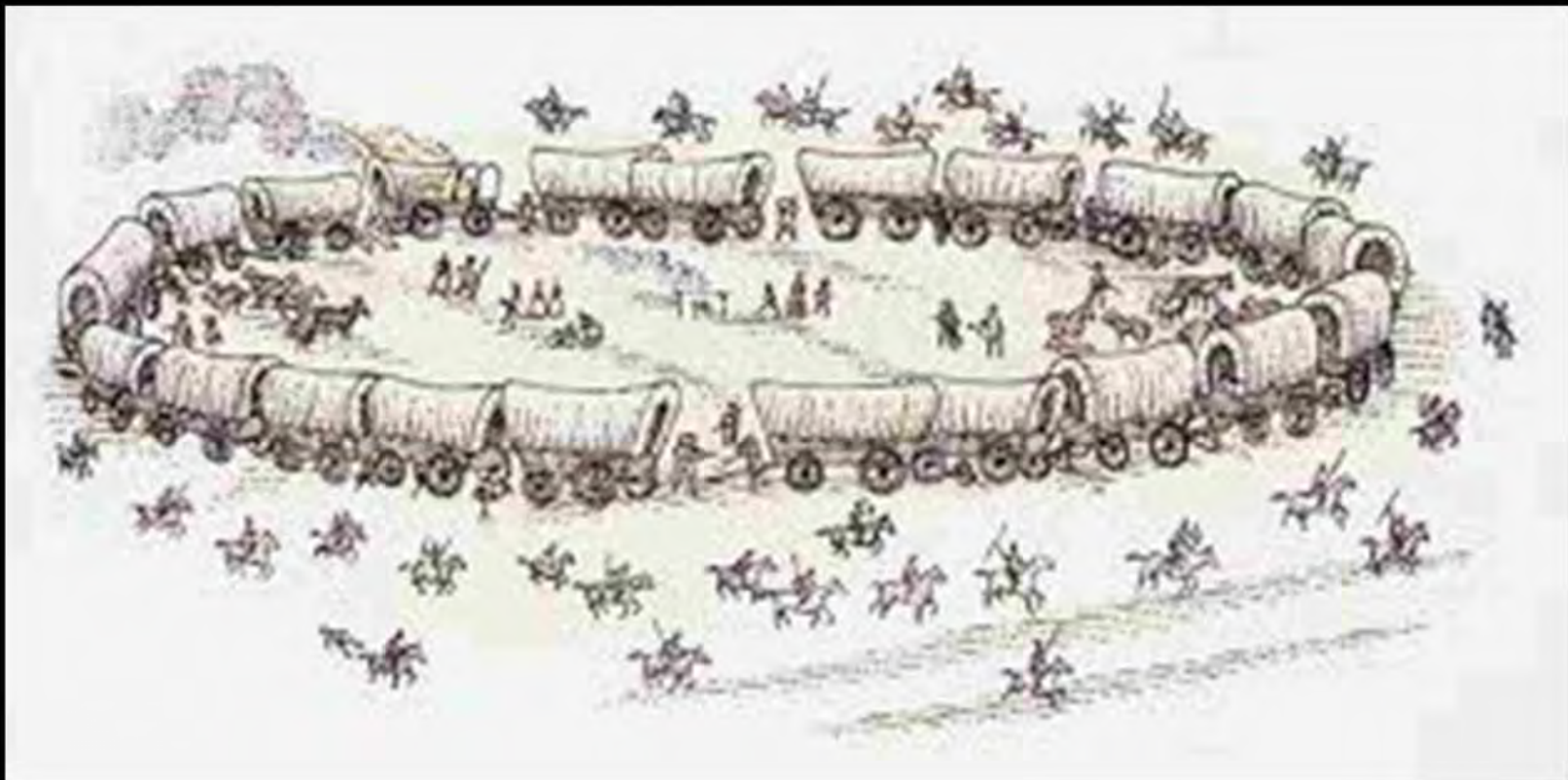


# Distinction Between Products

- Handling controls versus non-controls



# Maintain the Closed System of Distribution – United Front







# Fixing A National Problem

## The 3 Ps

- Position
- Perseverance
- Power



# Distributors Have Great Power

- Individually and collectively
  - Your DEA registration
  - Ensure timely distribution to prevent an uninterrupted supply; and
  - You control the supply to downstream customers





**“With Great Power Comes Great  
Responsibility”** *Voltaire 18<sup>th</sup> Century*



# “Know Your Customer”

- Legal obligation?
- To what extent?
- Good business practice
  - Leveraging your sales personnel
- Internal vs external information





# Detecting Suspicious Orders

- Use of Robust Systems
  - Must remain vigilant / keep abreast of evolving or emerging trends.
  - Identify “red flags” associated with evolving or emerging trends quickly
  - Adaptability of your SOM program to evolving or emerging trends



# Detecting Suspicious Orders

- Do not rely solely on thresholds or algorithms as a shortcut to detecting suspicious orders
- Most importantly, USE your system
  - Cannot ignore warning signs
  - Listen to employees when they do identify suspicious orders.





# Employees

- What is their background or experience?
- Proper Training
  - Initial
  - Updated
  - Training the right personnel
    - Company's Leadership and Field Managers
    - Sales reps
    - Regulatory/compliance personnel

airWork

Look

Make

A/for  
Simple

Make

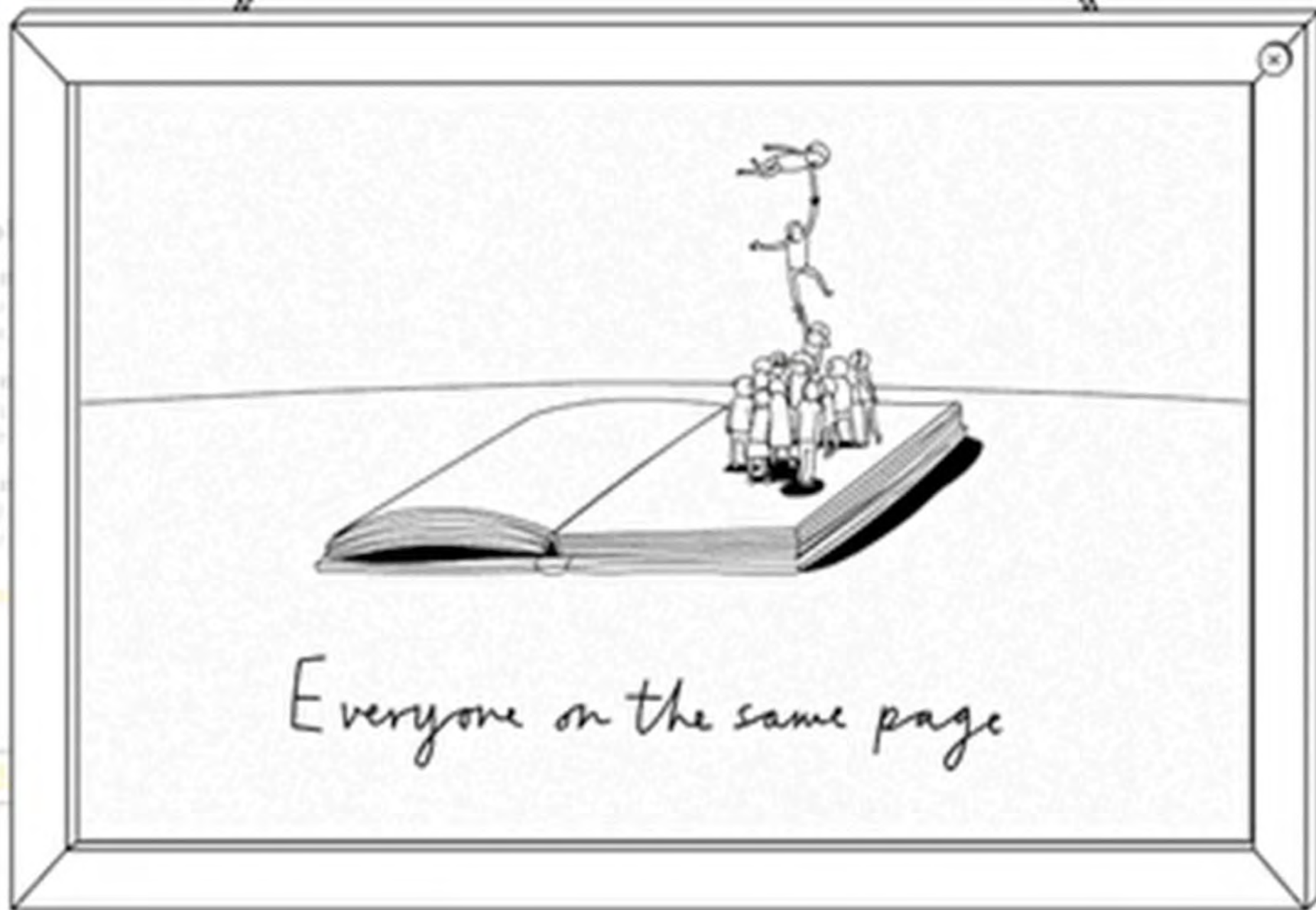
Simple  
Simple

Make

Make  
Simple

LEARN

Go







# Keeping Your Eye on the Ball

- Market dynamics can affect due diligence efforts.  
(shifting to different drugs based upon availability, new drugs or tamper-resistant formulations)
- Newly enacted laws can create shifts in diversion methods
- Cannot always rely on what your customers say to dispel a suspicious order. *“Trust, but verify”*



# What Impacts Diversion?

- New technology – the Internet
  - Rogue Internet pharmacies
  - Dissemination of information, both good and bad, at lightning speed





# What Else Impacts Diversion?

- Compliance!!!!!!
  - The checks and balances created by the Controlled Substances Act work
  - Registrants are a force-multiplier
  - Without sustained sources of supply major diversion schemes wither away



# Newton's Law of Physics

## Need for Vigilance

- Increase in DEA enforcement actions
- Changes in Florida law
- Pain clinic issue became a retail pharmacy issue
  - Pharmacies affiliated with the clinic or
  - To any retail pharmacy with oxycodone in supply
  - Further shift to nationwide mail order pharmacies
- Disruption of oxycodone supply
  - Abuse of hydromorphone increased



## **Speaker Notes for Slide 47**

Bullet 1: Operations: Pill Street Blues; Pill Nation I and II; Juice Doctor  
Increased enforcement action against wholesalers/distributors; impact on supply



# Positive Trends?

SAMHSA NSDUH data: The number of persons 12 years and older abusing pain relievers:

- 2012 – 4.9 million
- 2011 – 4.5 million
- 2010 – 5.1 million
- 2009 – 5.3 million
- 2004 – 4.3 million





# Positive Trends con't

## Florida Medical Examiner's Office data:

### ➤ Oxycodone related deaths

- 2012 – 735
- 2011 – 1,247
- 2010 – 1,516

### ➤ Benzodiazepines

- 2012 – 1,337
- 2011 – 1,950
- 2010 – 1,726

Florida Department of Law Enforcement, *“Drugs Identified in Deceased Persons by Florida Medical Examiners 2012 Report”*, September 2013



# Working in Today's Environment

- Recognizing where we are relative to prescription drug diversion and abuse
- Understanding who can make the greatest impact
- Level playing field across the industry

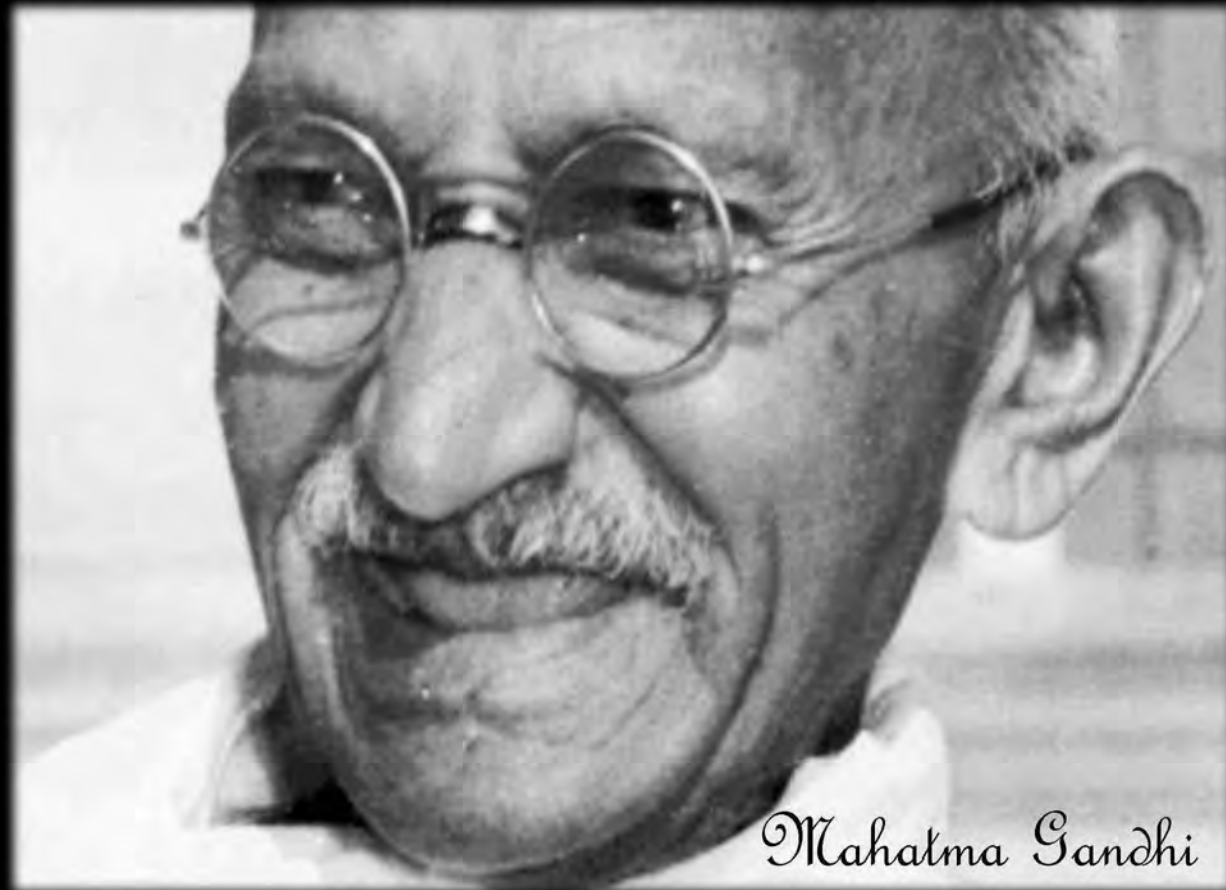




# The irony of prescription drugs



**“The future  
depends on  
what you do  
today”**



*Mahatma Gandhi*





# Thank You!

Contact Information:

Gary Boggs

(313) 670-0536

Email: [gb3242@gmail.com](mailto:gb3242@gmail.com)